84-290

No. 84-____

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

ORTHO PHARMACEUTICAL CORPORATION,
Petitioner,

—v.—

CAROL LYNN WOODERSON,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF THE STATE OF KANSAS

APPENDICES

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APPENDIX A

No. 55,655

CAROL LYNN WOODERSON,
Appellee,

v.

ORTHO PHARMACEUTICAL CORPORATION,
Appellant.

SYLLABUS BY THE COURT

1.

When a verdict is attacked for insufficiency of the evidence, the duty of the appellate court extends only to a search of the record for the purpose of determining whether there is any competent substantial evidence to support the findings. The appellate court will not weigh the evidence or pass upon the credibility of the witnesses. Under

these circumstances, the reviewing court must review the evidence in the light most favorable to the party prevailing below.

2.

"Substantial evidence" is defined as evidence which possesses both relevance and substance and which furnishes a substantial basis of fact from which the issues can reasonably be resolved.

3.

The manufacturer of ethical or prescription drugs has a duty to give timely and adequate warnings to the medical profession of any dangerous side effects

produced by its drugs of which it knows, or has reason to know.

4.

The duty to warn must be commensurate with the seriousness of the danger. The greater the danger, the greater the duty.

5.

Although the duty of the ethical drug manufacturer is ordinarily to warn the doctor rather than the patient, the manufacturer is directly liable to the patient for a breach of such duty.

6.

In the case of drug manufacturers, the standard of constructive knowledge is that of an expert in that particular field.

7.

Because a manufacturer cannot be required to warn of a risk unknown to science, the knowledge chargeable to the manufacturer of an ethical drug must be limited to that of the period during which the plaintiff was using the product in question.

8.

The duty to warn is a continuous one, requiring the manufacturer to keep abreast of the current state of knowledge relevant to its products as gained through research, adverse reaction reports, scientific literature, and other available methods.

9.

An adequate warning is one reasonable under the circumstances.

10.

Where scientific or medical evidence exists tending to show that a certain

danger is associated with use of a drug, the manufacturer may not ignore or discount that information in drafting its warning solely because it finds it to be unconvincing.

11.

There is a presumption that an adequate warning would be heeded. This operates to the benefit of a manufacturer where adequate warnings are in fact given. Where warnings are inadequate, however, the presumption is in essence a presumption of causation.

12.

What a doctor might or might not

have done had he or she been adequately warned is not an element plaintiff must prove as a part of his or her case.

13.

The intent and purpose of the legislature in adopting K.S.A. 60-258a is to impose individual liability for damages based on the proportionate fault of all of the parties to an occurrence which gave rise to the injuries and damages, whether or not those persons are joined as parties to the action.

14.

A party who seeks to reduce his percentage of fault by comparing the

fault of another party has the burden of proving the other party's fault by a preponderance of the evidence.

15.

Where there is no evidence of causal negligence on the part of a person, the question of that person's negligence need not be submitted to the jury.

16.

Punitive damages are permitted whenever the elements of fraud, malice, gross negligence, or oppression mingle in the controversy.

17.

Punitive damages are allowed not because of any special merit in the injured party's case, but are imposed to punish the wrongdoer for malicious, vindictive or willful and wanton invasion of the injured party's rights, the purpose being to restrain and deter others from the commission of like wrongs.

Appeal from Sedgwick District Court; DAVID P. CALVERT, judge. Opinion filed April 27, 1984. Affirmed.

David F. Dobbins, of Patterson, Belknap, Webb & Tyler, of New York, New York, argued the cause, and Donald R.

Newkirk, of Fleeson, Gooing, Coulson & Kitch, of Wichita, was on the briefs for appellant.

Gerald L. Michaud, of Michaud, Cordry, Michaud, Hutton & Hutton, of Wichita, argued the cause, and Andrew H. Hutton and Dwight A. Corrin, of the same firm, were with him on the brief for appellee.

The opinion of the court was delivered by

MILLER, J.: Plaintiff, Carol Lynn Wooderson, brought this action in the District Court of Sedgwick County for damages for personal injuries which she claims resulted from her ingestion, over a period of years, of the oral contra-

ceptive Ortho-Novum 1/80, manufactured by the defendant, Ortho Pharmaceutical Corporation (Ortho). At the conclusion of a six-week trial, the jury returned a verdict and the court entered judgment for plaintiff and against Ortho for actual damages of $2,000,000 and punitive damages of $2,750,000. Ortho appeals. The primary issues are whether there was sufficient competent evidence to support the verdict, and whether the trial court properly submitted the matter of punitive damages to the jury. Other issues will be stated in the opinion.

Carol Lynn Wooderson consulted Dr. Richard L. Hermes of Lawrence, Kansas, a physician specializing in obstetrics and gynecology, in the fall of 1972.

She was planning to be married and wanted some method of contraception. Dr. Hermes prescribed an oral contraceptive (o.c.), Ortho-Novum 1/80, manufactured by the defendant. This is an "ethical" drug, one obtainable only upon prescription, as distinguished from a "proprietary" or "patent" drug, one sold over the counter. Plaintiff was in good health at that time; her blood pressure was 100/56, and she had never had any problems with her kidneys or with high blood pressure. She took Ortho-Novum 1/80, as prescribed by her physician, continuously from the fall of 1972 until June 1976, with the exception of about thirty days in early 1974 when she had a rash on her hand and a physician suggested that she stop taking the pill until the rash went away. She

saw Dr. Hermes in December 1974; his notes reveal nothing remarkable about her health at that time except that her blood pressure was 130/80. The prescription for Ortho-Novum 1/80 was extended for another year. Mrs. Wooderson next saw the doctor in January 1976. His notes reveal nothing remarkable except that her blood pressure was 120/90. She had a cold, and Tuss-Ornade was prescribed for that. The Ortho-Novum 1/80 prescription was also extended for one year. On May 4, 1976, she called Dr. Hermes; she still had a cold, and he called in a prescription for Tuss-Ornade. On June 25, 1976, she again called him. She reported stomach pains and vomiting. Medication to stop the vomiting was prescribed, as was bed rest. Dr. Hermes advised her to

go to the emergencv room at the hospital if she had no relief by that night. Next, on June 28, 1976, Mrs. Wooderson went to the office. Dr. Hermes was not in, and she was examined by one of his associates, Dr. Howard Wilcox. Her blood pressure was 160/88. She complained of abdominal pain, nausea, dizziness, headaches and weakness. She felt like she was coming down with the flu. Dr. Wilcox took her off of the oral contraceptives and prescribed Equagesic. On the following day, she called Dr. Wilcox. She still had headaches, felt weak, was short of breath, and had a sore throat and cough. He directed her to continue with the Tuss-Ornade and the Equagesic. On June 30, she called the office and talked with Dr. Buck, another

associate. He authorized a refill of the Tuss-Ornade prescription. Two days later, on July 2, she saw Dr. Wilcox in his office. She was still vomiting; she complained of exhaustion upon slight exertion; her legs ached; and she had a sore throat but no fever. Her blood pressure had reached 186/104. Dr. Wilcox ordered some tests and later that same day referred her to Dr. Reid, an internist, who examined her and saw all of the laboratory reports. He directed her to the Lawrence Memorial Hospital, which she entered on July 2. Her blood pressure was 202/102. She was diagnosed as having chronic renal disease. Two days later, on Sunday, July 4, 1976, she was transferred by ambulance to the K. U. Medical Center in Kansas City, Kansas.

Upon her arrival at the medical center, she was described as being in poor condition, and she was initially diagnosed as suffering from "renal failure." Peritoneal dialysis was commenced immediately. A few days later, surgery was performed so that she could be connected to the hemodialysis machine. Her kidneys had utterly failed, and she was completely dependent upon hemodialysis. She was released from the K. U. Medical Center on July 28, 1976. The hospital records upon her discharge contain the following case summary:

> "FINAL DIAGNOSIS: Renal failure secondary to hemolytic uremic syndrome, oral contraceptive induced.
> Hypertension, volume dependent.
> Congestive heart failure secondary to volume overload.
> Anemia secondary to #1.

"OPERATIONS AND PROCEDURES: Peritoneal dialysis. Renal biopsy, open. External leg shunt. Internal fistula placement in the left arm.

"DISPOSITION: The patient is discharged on the following medications - Inderal, 20 mg. p.o. q.i.d.; Atarax, 25 mg. p.o. p.r.n. itching Dalmane, 15 mg. p.o. p.r.n. sleep; Coumadin, 2.5 mg. p.o. daily; Colace, 1 tablet p.o. t.i.d; Alu-Caps, 2 tablets p.o. t.i.d.; Renal Vitamin, 1 p.o. daily. The patient will be returning to the Outpatient Dialysis Clinic for thrice weekly in-center dialysis. The patient and husband will undergo home dialysis training in the late summer or early fall.

"PROGNOSIS: Fair."

After plaintiff was discharged, she had to return to the hospital three times weekly from her home in Lawrence for dialysis treatments. In October 1976, she and her husband travelled to the medical center daily for four weeks and took training for home dialysis. In

November, plaintiff got a home dialysis machine, and thereafter her husband gave her the treatments at home. At first, the dialysis took six hours; later it was reduced to five hours, then to four hours. Mrs. Wooderson continued to have blood pressure problems until both of her kidneys were removed surgically on February 1, 1977. She had eye problems, for which she was hospitalized and treated regularly. On March 22, 1977, she had a kidney transplant from her brother. This was unsuccessful; she rejected the donated kidney. It was removed on April 12, 1977.

On May 3, 1981, following dialysis, the plaintiff had very low blood pressure and stomach cramps. The latter grew pro-

gressively worse. She was taken to the Lawrence Memorial Hospital and then transferred by ambulance to the University of Kansas Medical Center on the following morning. Upon arrival, she was described as having severe abdominal pain and having the classic symptoms of peritonitis. Exploratory abdominal surgery was performed immediately. Roughly one-third of her large intestine, the right colon, was found to be gangrenous, and was removed. Bacteria that normally live inside the intestine were found outside, in the peritoneal cavity, and this was the cause of the peritonitis or generalized infection in the abdomen. The surgeon who performed this operation, Dr. George Emory Pierce, M.D., concluded that the plaintiff's difficulty with the

bowel was due to inadequate blood supply to the intestine. This, in turn, was caused by the low blood pressure following dialysis. Mrs. Wooderson recovered well from this abdominal surgery, and was discharged from the hospital on May 22, 1981.

A second kidney transplant performed in November 1981 has proven successful. Since receiving that kidney, plaintiff has had only one minor rejection, and she has not had to go back on the dialysis machine. At the time of trial, she had gotten along well with the new kidney for some thirteen months. Her blood pressure has not been a problem. She still has blind spots in the right eye, and she is taking Imuran and Prednisone, which are

steroids or immunosuppressant drugs, as well as a renal vitamin and Colace, a stool softener. She will have to take the steroids so long as she retains the donated kidney. Because of the risk involved, she will not have children.

Plaintiff's actual out-of-pocket medical expenses up to the time of trial, plus loss of wages and mileage from her home to and from the hospital, exceeded $215,000. Damages sustained and not covered within the monetary figure include future drug expenses (estimated at $28,800), loss of both kidneys, cataracts in both eyes, increased risk of cancer because of the continued ingestion of steroids, inability to have children, loss of blood flow to part of the large

intestine necessitating major abdominal surgery and removal of part of the intestine, risk of further intestinal surgery, and mental anguish, pain and suffering caused by the extended hospitalization, repeated operations, hemodialysis for five and one-half years, loss of her brother's donated kidney, and some fifty-five blood transfusions. Ortho does not argue that the $2,000,000 awarded as compensatory damages is excessive, or that the amount of the award is not supported by the evidence. Instead, Ortho argues that there is no substantial evidence that the oral contraceptives caused plaintiff's kidney failure; that Ortho had no duty to warn of the risk of hemolytic uremic syndrome (HUS); and that even if it did have the duty to warn, its

failure to warn bore no causal relationship to Dr. Hermes' decision to prescribe Ortho-Novum 1/80 for the plaintiff. Thus, Ortho's position is not that plaintiff did not sustain the injuries and damages claimed, but that Ortho did not cause them to occur and is therefore not responsible. It challenges causation and responsibility, not injury.

SUFFICIENCY OF THE EVIDENCE

The rules under which we review the evidence, when challenged as to sufficiency to support a verdict, are familiar. In Cantrell v. R. D. Werner Co., 226 Kan. 681, 684, 602 P.2d 1326 (1979), we said:

> "It has long been the rule that when a verdict is attacked for insufficiency of the evidence, 'the duty of the appellate court extends only to a search of the record for the purpose of determining whether there is any competent substantial evidence to support the findings. The appellate court will not weigh the evidence or pass upon the credibility of the witnesses. Under these circumstances, the reviewing court must review the evidence in the light most favorable to the party prevailing below.' Craig v. Hamilton, 221 Kan. 311, 313, 559 P.2d 796 (1977)."

See also Hand Realty Co. v. Meyers, 234 Kan. 304, 306, 672 P.2d 583 (1983).

Similarly, in Timsah v. General Motors Corp., 225 Kan. 305, 591 P.2d 154 (1979), the rule is concisely stated in Syllabus ¶ 1:

> "When a verdict is attacked on the ground it is contrary to the evidence, it is not the function of this court on appeal to weigh the

> evidence or pass on the credibility of the witnesses. If the evidence with all reasonable inferences to be drawn therefrom, when considered in a light most favorable to the successful party below, will support the verdict this court should not intervene."

"Substantial evidence" is defined as evidence which possesses both relevance and substance and which furnishes a substantial basis of fact from which the issues can reasonably be resolved. In re Certif. of Need App. by Community Psychiatric Centers, Inc., 234 Kan. 802, 806, 676 P.2d 107 (1984); Haddock v. U.S.D. No. 462, 233 Kan. 66, 661 P.2d 368 (1983); Kelly v. Kansas City, Kansas Community College, 231 Kan. 751, 648 P.2d 225 (1982). Stated in another way, "substantial evidence" is such legal and

relevant evidence as a reasonable person might accept as being sufficient to support a conclusion. Kansas Dept. of Health & Environment v. Banks, 230 Kan. 169, 630 P.2d 1131 (1981). In conformity with these rules, we now consider the evidence in the light most favorable to the successful party.

THE PILL AS CAUSATION

Was there substantial, competent evidence that the oral contraceptive Ortho-Novum 1/80 caused plaintiff's hemolytic uremic syndrome (HUS) and the consequent loss of her kidneys? That is the first issue. Plaintiff, in support of her claim that the drug caused her HUS, presented three specialists, Dr. Dennis

Diederich and Dr. Frank Cuppage, both physicians and members of the teaching staff at the K. U. Medical Center, and Dr. John Gabourel, Ph.D., a professor of pharmacology at the Oregon Health Sciences University, formerly the University of Oregon School of Medicine. Through these witnesses she presented many articles published in medical and scientific journals, both here and abroad.

First, a word about hemolytic uremic syndrome, or HUS. A syndrome is not a disease; it is a set or constellation of symptoms which occur together, and which help the physician recognize the condition and set it apart from less serious conditions or diseases indicated when

only one--or at least less than all--of the symptoms are present. "Hemolytic" means causing hemolysis, the destruction of the red blood cells. "Uremic" means caused by or pertaining to uremia, the presence of urine in the blood and the toxic condition thereby produced. Hemolytic uremic syndrome usually first manifests itself with flu-like symptoms--headache, nausea, fatigue, sometimes fever--and with constantly increasing blood pressure. The onset is rapid. HUS is recognizable through three main symptoms or features. These are: (1) acute kidney failure; (2) thrombocytopenia, a marked decrease in the number of blood platelets, small colorless cells in the blood which assist in the coagulation or clotting of the blood; and (3) hemolytic

anemia, a condition in which the blood is markedly deficient in the number of red blood cells. These three symptoms, kidney failure (resulting in uremia or the presence of urinary constituents in the blood), thrombocytopenia, and hemolytic anemia, can be detected through examination of the blood. The syndrome is also reflected in abnormality in the lining or intima of the small blood vessels in the kidney; this causes hemolysis or destruction of the red blood cells moving across the injured lining. Abnormality of the blood vessels of the kidney may be detected pathologically. HUS is extremely serious. Its course is described as being relentlessly downhill, with irreversible kidney failure the usual result.

Dr. Diederich is a professor of medicine in the department of internal medicine at K. U. Medical Center. He is board-certified in internal medicine and also in nephrology. His practice, and the area in which he teaches, consists of diagnosing various problems with the kidney, trying to determine the cause of the kidney ailment, and treating the condition. He has been in the nephrology section of the department of internal medicine at the K. U. Medical Center since 1969. He was alerted by a telephone call from plaintiff's physician in Lawrence, and was present when she arrived at the medical center on July 4, 1976. She was taken directly to the intensive care unit. There, Dr. Diederich observed that her blood pres-

sure was very high. She showed evidence of circulatory overload. Her heart was beating hard, her pulse was pounding and her veins were distended. Her hands and feet were swollen. The breath sounds reflected moisture in the lungs. She was making very, very small amounts of urine, and a catheter in her bladder demonstrated that there was no flow of new urine being made by her kidneys. The blood vessels in her eyes evidenced increased tension. Peritoneal dialysis was employed to relieve the pressure and correct the blood by filtration. Blood tests disclosed that she had less than half of the expected normal amount of red blood cells in a sample of her blood, and a low white blood cell count--2,500 rather than the 4,000 to 6,000 which

would normally be found. Twelve to fifteen pounds of fluid was removed by peritoneal dialysis. Later in the week, a small specimen was taken surgically from plaintiff's kidney, and this was microscopically examined.

Dr. Diederich was furnished with a history of the patient and of the patient's family. He carefully checked on and ruled out infection or any of the other possible causes for plaintiff's condition. He testified that oral contraceptives cause changes in the blood vessels in the kidney. He expressed the opinion that the oral contraceptive taken by the plaintiff was responsible for the destruction of her kidneys and the generation of her malignant hypertension.

When Carol Wooderson first entered the hospital, Dr. Diederich thought that she was suffering from HUS, brought on by the oral contraceptives which she had been taking. He still thought so when she was released from the hospital on July 28, 1976. Thereafter, he read many additional published articles on the subject in various medical journals, dozens of which were received in evidence in this case. When he testified at the trial, Dr. Diederich still believed that the oral contraceptives taken by Carol Wooderson caused her HUS and the resulting loss of her kidneys, the eye problems, and the loss of a section of her intestine.

The testimony of Dr. Francis Edward

Cuppage, M.D., was presented by videotape deposition. Dr. Cuppage is a pathologist, and his area of special interest is in kidney or renal disease. He has been on the teaching staff at the University of Kansas Medical School since 1967, and he has been a full professor since 1973. He practices medicine, teaches, and does research in acute renal failure. He is a board-certified pathologist, and he has published some fifty-four articles in medical journals, most of them related to the kidney. Some are also related to blood supply. He had no direct contact with the plaintiff and had not seen her before his deposition was taken. He is the pathologist in charge of renal biopsies at the K. U. Medical Center. As such, and at the request of

Dr. Diederich, Dr. Cuppage examined a portion of the plaintiff's kidney on July 8, 1976. This portion had been removed by Dr. Arlo Hermrick, a surgeon, by a procedure known as kidney wedge biopsy. One sample was examined in the usual method by microscope, and the other was examined by electron microscopy. When Dr. Cuppage first microscopically examined this tissue, he had not read plaintiff's clinical history and laboratory findings. He had read these materials when later studies were conducted on plaintiff's kidneys, after their removal in early 1977.

Dr. Cuppage explained the microscope slides prepared from the biopsy of Carol Wooderson's kidneys, and he pointed out

the major areas of damage, both in the blood vessels and in the glomeruli, the filters of the kidney. He explained why the slides rule out most of the things which might cause kidney damage. Then Dr. Cuppage expressed the opinion that the contraceptive pill, Ortho-Novum 1/80, can produce an alteration in the blood vessels. He thought that the most probable cause of plaintiff's HUS and her resulting health problems was blood vessel lesions produced by oral contraceptives. The lesions in the small blood vessels in the kidneys came first; hypertension and damage to the glomeruli followed as a result of the vascular lesions. He stated that he was more firmly convinced at the time he was giving his testimony that his original diagnosis was

correct than he had been when he made it. All of the pathological and clinical information which he received later solidified his opinion.

John Gabourel, Ph.D., a professor of pharmacology from the Oregon Health Sciences University, testified at length. He received his Ph.D. degree in pharmacology at the University of Rochester in 1957. He has conducted research on many subjects and has had national level research support for many years. He teaches medical students and nurses at the university, and also participates in continuing education courses for the practicing physicians of his state. Included in the areas he teaches is systematic pharmacology or organ system

pharmacology, which deals with the specific effect of drugs on different tissues and organs of the body. He has authored some thirty-one major publications, plus a lesser number of short articles. In preparing to testify in this case, he read abstracted portions of the medical records of the plaintiff and many original articles that had been obtained previously by Dr. Diederich. He ran a Med.-Line computer search of his own, discovered and read additional articles, consulted Harrison's Textbook of Medicine, and in general read everything that he could find that had been published relating to HUS and particularly to its occurrence in women who have been taking oral contraceptives. He testified that he had spent almost all of

the three weeks before he testified reading and thinking about HUS, running more computer searches in different areas, and talking to other people in specialized areas, including officials of the Food and Drug Administration. He expressed the opinion that Ortho-Novum 1/80, in some women, causes malignant hypertension, vessel wall damage, HUS, and permanent failure of and loss of the kidneys. It was his professional opinion that Ortho-Novum 1/80 caused Carol Wooderson's HUS and the loss of her kidneys.

Among the reasons why this witness concluded that Ortho-Novum 1/80 caused plaintiff's HUS were: (1) Plaintiff took the oral contraceptives long enough for

development of lesions of the type identified by Dr. Nelson Irey as being caused by oral contraceptives; (2) no other agency with known association to HUS was present; (3) the known effects of estrogen (a component of Ortho-Novum 1/80) are compatible with (a) the alteration in blood vessel structure and (b) the enhancement of platelet adhesion and aggregation; (4) there were twenty-one reported cases of women on oral contraceptives having HUS before plaintiff, and at the time of trial there were thirty-nine patient cases reported wherein oral contraceptives were associated with HUS; (5) in two of the reports, there was a "re-challenge"--women who were on oral contraceptives and showed symptoms of HUS were taken off the oral contraceptives

and apparently recovered, were put back on oral contraceptives and suffered severe recurrence of HUS; (6) the pathological examination and report done in February 1977, after plaintiff's bilateral nephrectomy, was consistent with HUS. Dr. Gabourel ruled out as causative agents all of the other drugs which plaintiff had taken prior to the onset of her HUS. It was his opinion that Ortho-Novum 1/80 caused inflammation and occlusion of the inner wall of the tiny arteries in her kidneys. This was followed by kidney failure and then malignant hypertension. He suggested that her January 1976 blood pressure of 120/90 is highly significant, a 30mm rise over her pre-oral contraceptive measurement. Thus it was his opinion that this catastrophy

could have been avoided if her physicians had been properly warned. Warnings would have alerted her physicians to monitor her blood pressure more closely and to conduct various urine and renal function tests earlier in 1976. Early detection could have prevented the irreversible kidney failure.

The testimony of Dr. Diederich and Dr. Gabourel extends through ten volumes of trial transcript. Dr. Cuppage's deposition is also a lengthy document. Other physicians also testified. The brief summaries above reflect but a very small portion of the plaintiff's evidence in this case. Ortho contends that plaintiff's proof of medical causation is "conjectured" and "based on a diagnosis

of exclusion." Upon reviewing this entire record, however, it appears to us that the proof of medical causation is detailed, logical, and based upon scientific studies, commencing with those of pathologist Nelson Irey. One of the requisites for arriving at a conclusion as to cause is to consider all possible causes. Plaintiff's expert witnesses did this, and each gave in detail the reasons why Ortho-Novum 1/80 was the cause, and why each other possible cause of plaintiff's HUS had to be eliminated in this case. We conclude that there is an abundance of substantial, competent evidence to support the jury's finding that Ortho-Novum 1/80 caused the plaintiff's HUS, her acute kidney failure, and her resulting injuries and damages.

DUTY TO WARN

Ortho contends that it had no duty to add to the prescribing instructions for Ortho-Novum 1/80 statement that there might be an association between the use of that product and HUS, malignant hypertension, or acute renal failure. In support of this contention, it cites Restatement (Second) of Torts § 402A (1965), including the comments thereto, and Lindquist v. Ayerst Laboratories, Inc., 227 Kan. 308, 319, 607 P.2d 1339 (1980). Lindquist was a products liability and medical malpractice case brought against Ayerst Laboratories, Inc., the manufacturer of an anesthetic which had been administered to the decedent, and the two physicians who had

administered the anesthetic. Verdict had been entered for the defendants and plaintiff appealed. In the course of the opinion, we said:

> "[T]he jury was properly instructed regarding the doctrine of strict liability expressed in Restatement (Second) of Torts § 402A (1965). The jury was instructed to find Ayerst liable provided they found the drug was in a defective condition and unreasonably dangerous to persons who might be expected to use it, where that defect caused or contributed to the death of Lindquist. The defective condition is the failure of Ayerst to properly warn and instruct the medical profession with respect to the use and possible consequences of the use of Fluothane." 227 Kan. at 319.

Section 402A of the Restatement, together with the applicable portions of Comment j thereunder, read as follows:

"§402A. Special Liability of Seller of Product for Physical Harm to User or Consumer

"(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

"(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

> j. Directions or warning. . . . Where, however, the product contains an ingredient to which a substantial number of the population are allergic, and the ingredient is one whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it, if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger. Likewise in the case of poisonous drugs, or those unduly dangerous for other reasons, warning as to use may be required." (Emphasis supplied.)

Defendant seizes upon that portion of the comment reading "if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge . . . ." Ortho contends, in essence, that an ethical (prescription) drug manufacturer is not

bound to provide warnings until the occurrence of side effects is so frequent and the evidence of causation so clear-cut that the drug maker is itself convinced that the drug causes or contributes to such problems. This, we conclude, is not the law. A drug manufacturer's duty to warn is discussed and the rules are stated in numerous cases. A leading case in this field is McEwen v. Ortho Pharmaceutical, 270 Or. 375, 528 P.2d 522 (1974). Plaintiff McEwen brought suit against Ortho and Syntex for their alleged failure to give appropriate warning to the medical profession of dangers which the manufacturers knew or had reason to know were inherent in the use of their products. Plaintiff recovered judgment and defendants appealed.

In affirming the judgment, the court said:

"I. DEFENDANTS' DUTY TO WARN PLAINTIFF'S DOCTORS

1. There is no question here of any defect in the manufacture of defendants' oral contraceptives, nor of their efficacy when taken as prescribed. It is well settled, however, that the manufacturer of ethical drugs bears the additional duty of making timely and adequate warnings to the medical profession of any dangerous side effects produced by its drugs of which it knows, or has reason to know. E.g., Sterling Drug, Inc. v. Cornish, 370 F2d 82 (8th Cir 1966); Parke-Davis & Co. v. Stromsodt, 411 F2d 1390 (8th Cir 1969); Stevens v. Parke, Davis & Co., 9 Cal 3d 51, 107 Cal Rptr 45, 507 P.2d 653 (1973); Love v. Wolf, 226 Cal App 2d 378, 38 Cal Rptr 183 (1964); Krug v. Sterling Drug, Inc., 416 SW2d 143 (Mo Sup Ct 1967); see 2 Restatement (Second) of Torts 300, §388 (1965).

"The duty of the ethical drug manufacturer to warn is limited to those dangers which the manufacturer knows, or has reason to know, are inherent in the use of its drug.

However, the drug manufacturer is treated as an expert in its particular field, and is under a 'continuous duty * * * to keep abreast of scientific developments touching upon the manufacturer's product and to notify the medical profession of any additional side effects discovered from its use.' Schenebeck v. Sterling Drug, Inc., 423 F2d 919, 922 (8th Cir 1970); accord O'Hare v. Merck & Co., 381 F2d 286, 291 (8th Cir 1967). The drug manufacturer's duty to warn is, therefore, commensurate not only with its actual knowledge gained from research and adverse reaction reports but also with its constructive knowledge as measured by scientific literature and other available means of communication.

"Although the duty of the ethical drug manufacturer is to warn the doctor, rather than the patient, the manufacturer is directly liable to the patient for a breach of such duty. See Schenebeck v. Sterling Drug, Inc., supra; Love v. Wolf, supra. The manufacturer's compliance with this duty enables the prescribing physician to balance the risk of possible harm against the benefits to be gained by the patient's use of that drug. Moreover, as observed by the court in Sterling Drug, Inc. v. Cornish, supra 370 F2d at 85:

"'*** [T]he purchaser's doctor is a learned intermediary between the purchaser and the manufacturer. If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided. This is particularly true if the injury takes place slowly ***.'

"Although the ethical drug manufacturer's duty to warn has been discussed most often with reference to the prescribing physician, the above reasoning applies with equal force to the treating physician. It is especially important that the treating doctor receive the manufacturer's warnings where it is impossible to predict in advance whether a particular patient is apt to suffer adverse effects from a drug, since the treating doctor may be more likely to observe the actual symptoms of the drug's untoward consequences. If the prescribing physician is entitled to make an informed choice in deciding whether the patient should begin taking a prescription drug, it follows that a treating physician should have the same information in making his decision as to whether the patient should stop taking that drug.

"The duty of the ethical drug manufacturer to warn extends, then, to all members of thc medical profession who come into contact with the patient in a decision-making capacity. To satisfy this duty, the manufacturer must utilize methods of warning which will be reasonably effective, taking into account both the seriousness of the drug's adverse effects and the difficulties inherent in bringing such information to the attention of a group as large and diverse as the medical profession. See Sterling Drug, Inc. v. Yarrow, 408 F2d 978 (8th Cir 1969). The warning should be sufficient to apprise the general practitioner as well as the 'unusually sophisticated medical man' of the dangerous propensities of the drug. Parke-Davis & Co. v. Stromsodt, 411 F2d 1390, 1400 (8th Cir 1969). In short, 'it is incumbent upon the manufacturer to bring the warning home to the doctor.' Rheingold, Products Liability--The Ethical Drug Manufacturer's Liability, 18 Rutgers U L Rev 947, 993 (1964).

"It has been suggested, however, that the manufacturer of a prescription drug should be under no duty to warn the medical profession that its product is dangerous when used by certain allergic or hypersensitive users. It is unreason-

able, so the argument runs, to impose upon the manufacturer a duty to warn doctors of dangers threatening a statistically insignificant number of users. We find this argument unpersuasive.

"In the field of negligence the duty to warn is limited to those dangerous propensities of the drug of which the manufacturer knows, or has reason to know. If allergic reactions are harder to anticipate, this should be taken into account in evaluating the manufacturer's knowledge. It must be remembered that the negligence liability of the ethical drug manufacturer is restricted to those dangers which <u>are</u> foreseeable.

"Furthermore, to simply conclude that it is unreasonable to impose liability where the known danger threatens only a statistically small percentage of the drug's users is to beg the very question of negligence. The size of the class of endangered persons is one--albeit only one--of the factors to be considered in deciding whether the manufacturer's warnings were, in fact, reasonable.

"The ethical drug manufacturer is, then, subject to a duty to warn the medical profession of untoward effects which the manufacturer

> knows, or has reason to know, are inherent in the use of its drug. Sterling Drug, Inc. v. Cornish, supra 370 F2d 82; Parke-Davis & Co. v. Stromsodt, supra 411 F2d 1390; Basko v. Sterling Drug, Inc., 416 F2d 417 (2d Cir 1969); Love v. Wolf, supra 226 Cal App 2d 378; Krug v. Sterling Drug, Inc., supra 416 SW2d 143; cf. Davis v. Wyeth Laboratories, Inc., 399 F2d 121 (9th Cir 1968). See also Wright v. Carter Products, Inc., 244 F2d 53 (2d Cir 1957); Hungerholt v. Land O'Lakes Creameries, Inc., 209 F Supp 177 (D Minn 1962), aff'd 319 F2d 352 (8th Cir 1963); Gerkin v. Brown & Sehler Co., 177 Mich 45, 143 NW 48 (1913). But see Winthrop Laboratories Division of Sterling Drug, Inc. v. Crocker, 502 SW 2d 850 (Tex Civ App 1973)." 270 Or. at 385-390.

In determining whether there was a breach of defendant's duty, the Oregon court said:

> "Because the ethical drug manufacturer has only the duty to warn the medical profession of those adverse effects of which it knows, or has reason to know. the adequacy of the warnings given by each defendant

> depends upon the actual and constructive knowledge of that defendant before and during the period in which Mrs. McEwen used its drug. For Syntex, the relevant interval began on December 3, 1966, when plaintiff first took Norinyl, and ended on December 20, 1967, when she changed to Ortho-Novum oral contraceptives. From that date, plaintiff used Ortho-Novum until approximately December 22, 1968, and this is the relevant time span with reference to Ortho's knowledge.
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> . . . .
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> "Numerous studies, reports and other documents were admitted into evidence and discussed by the expert witnesses. Some of these materials support Mrs. McEwen's contention that defendants knew, or should have known, of the dangerous propensities of their oral contraceptives during the time plaintiff was using them." 270 Or. at 390-91.

Thereafter, the court discussed testimony of experts, a cooperative two-year oral drug safety study conducted by Ortho and Syntex, a 1965 article pub-

lished in Archives of Ophthalmology, and various package inserts. The court then stated:

> "Viewing all the testimonial and documentary evidence in its entirety, there was substantial evidence that each defendant knew, or should have known, that its oral contraceptive had a dangerous propensity to cause the kind of harm suffered by plaintiff. This is not to say that defendants did not produce substantial evidence tending to prove that they did not have such knowledge during the relevant times. Our sole function, however, has been completed by our determination that reasonable men might differ upon the point. It was for the trier of fact to resolve the conflict." 270 Or. at 395-96.

In Ortho Pharmaceutical v. Chapman, 180 Ind.App. 33, 388 N.E.2d 541 (1979), the Court of Appeals of Indiana, Fourth District, said:

"We are persuaded that the duty to warn under Comment k does not arise until the manufacturer knows or should know of the risk. [Citations omitted.] In the case of drug manufacturers, the standard of constructive knowledge is that of an expert in that particular field. Reyes v. Wyeth Laboratories, Inc. (5th Cir. 1974), 498 F.2d 1264 [citations omitted]. . . . [D]ates are 'vitally important' with respect to the duty to warn. Because a manufacturer cannot be required to warn of a risk unknown to science, the knowledge chargeable to him must be limited to that of the period during which the plaintiff was using the product in question. [Citations omitted.]

"A second important limitation on liability . . . applies to manufacturers of ethical [prescription] drugs. Since such drugs are available only by prescription, a manufacturer's duty to warn extends only to the medical profession, and not the ultimate users. [Citations omitted.] Terhune v. A. H. Robins Co. (1978), 90 Wash.2d 9, 577 P.2d 975. The rationale for this exception to the Restatement's general rule is that 'Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into

account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.'

Reyes v. Wyeth Laboratories, Inc., supra. The court in Terhune v. A. H. Robins Co., supra, elaborates further:

'The reasons for this rule should be obvious. Where a product is available only on prescription or through the services of a physician, the physician acts as a 'learned intermediary' between the manufacturer or seller and the patient. It is his duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician decides what facts should be told to the patient. Thus, if the product is properly labeled and carries the necessary instructions and warnings

to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient. It has also been suggested that the rule is made necessary by the fact that it is ordinarily difficult for the manufacturer to communicate directly with the consumer. (Footnote omitted.)'

"In summary, a proper warning under Comment k in the context of the facts at bar, communicates a risk attendant on the use of the product which is known to experts in the field during the period in which the product is used. It need only be directed to doctors, not patients who are the ultimate users.

. . . . .

"To summarize, a product which is faultlessly designed and manufactured may be nevertheless unreasonably dangerous within the meaning of §402A if not accompanied by proper warnings. A manufacturer can only be required to warn of risks known during the time in which the plaintiff was using the product in question, however he is charged with the knowledge of an expert in that

field. In the case of ethical drugs, the manufacturer's duty is discharged if adequate warning is given to doctors, who act as 'learned intermediaries' between the manufacturer and the ultimate user. To be adequate, a warning must be reasonable under the circumstances. As a practical matter, this is determined by application of negligence theory.

"As proof of the inadequacy of Ortho's warnings, Chapman offered into evidence the full text of the written warnings in question and expert testimony as to the state of knowledge in the medical profession at the time. Ortho argues that the plaintiff's expert was not qualified to give an expert opinion as to the adequacy of the warnings since he had no special training or experience in reading and writing warnings. This is not the test:

"'The true rule appears to be fairly stated in the case of Isenhour v. State, 1901, 157 Ind. 517, 528, 62 N.E. 40, 44, 87 Am.St.Rep. 228, in which this court said: "Courts have never undertaken to set up a standard of scientific knowledge by which the competency of a witness may be determined, and have not gone to the extent of holding that a scientific witness can only testify from facts learned by

him from personal demonstration. The general rule in such cases, in this state, at least, seems to be that, where a witness exhibits such a degree of knowledge, gained from experiments, observation, standard books, or other reliable source, as to make it appear that his opinion is of some value, he is entitled to testify leaving to the trial court, in the exercise of a sound discretion, the right to say when such knowledge is shown, and to the jury the right to say what the opinion is worth; and, as in all other cases of discretion, this court will review the action of the trial court only when that discretion clearly appears to have been abused."'

Illinois Steel Co. v. Fuller (1939), 216 Ind. 180, 23 N.E.2d 259, 263. Our review of this expert's qualifications convinces us that clearly there was no abuse of discretion in permitting his testimony. Regarding the state of knowledge in the medical profession at the time, the expert testified that 'statistics were being published to show the direct relationship of the oral contraceptive pill to an increased disposition in women to develop blood clotting. . . .' The expert then summarized several reports of studies. He was asked, 'Was there information in the year 1968 available to the defendant here from

these studies, you take the Wright Committee, the British Studies, the Hellman Reports, that did establish a relationship between the use of the pill and thrombophlebitis?' The expert responded 'yes.' The expert was then requested to read aloud the following portion of Ortho's 1968 Physicians Desk Reference entry for Ortho-Novum: 'No comparable studies are yet available in the United States. The British data, <u>especially as they indicate the magnitude of the increased risks</u> to the individual patient, <u>cannot be directly applied to women in other countries</u> in which the incidences of spontaneously occurring thromboembolic disease may be different.' (Emphasis added). The expert was asked to state his opinion of the adequacy of the warning. After objections, preliminary questions, a recess, and more objections, he stated that in his opinion the warnings were 'insufficient, incomplete and misleading.'" 180 Ind.App. at 42-44, 50-52.

Again, with reference to the manufacturer's duty to warn the Second Circuit in <u>Lindsay v. Ortho Pharmaceutical</u>

Corp., 637 F. 2d 87 (2d Cir. 1980), said:

> "The manufacturer's duty is to warn of all potential dangers which it knew, or in the exercise of reasonable care should have known, to exist. Baker v. St. Agnes Hospital, supra, 70 App.Div.2d at 405, 421 N.Y.S.2d 81; Tinnerholm v. Parke-Davis & Co., 285 F.Supp. 432, 451 (S.D.N.Y. 1968), aff'd on other grounds, 411 F.2d 48 (2d Cir. 1969). The duty is a continuous one, requiring the manufacturer to keep abreast of the current state of knowledge of its products as gained through research, adverse reaction reports, scientific literature, and other available methods. Baker v. St. Agnes Hospital, supra, 70 App.Div.2d at 406, 421 N.Y.S.2d 81. Except where FDA regulations otherwise provide, the manufacturer's duty is to warn the doctor, not the patient. The doctor acts as an 'informed intermediary' between the manufacturer and the patient, evaluating the patient's needs, assessing the risks and benefits of available drugs, prescribing one, and supervising its use. Wolfgruber v. Upjohn Co., supra, 72 App.Div.2d at 61, 423 N.Y.S.2d 95." 637 F.2d at 91.

Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652 (1st Cir. 1981), is another case in which the adequacy of warnings was involved. That court said:

> "An adequate warning is one reasonable under the circumstances. Sterling Drug, Inc v. Yarrow, 408 F.2d 978, 992, 993 (9th Cir. 1969); Ortho Pharmaceutical Corp. v. Chapman, 388 N.E.2d at 553. A warning may be inadequate in factual content, in expression of the facts, or in the method by which it is conveyed. Ortho Pharmaceutical Corp. v. Chapman, 388 N.E.2d at 552.
>
> "The adequacy of the warning must be judged in the light of what Ortho knew at the time Mrs. Brochu was actually taking Ortho-Novum 2 mg. The key document in this determination is a study conducted by Inman, Vessey, Westerholm, and Engelund and published in the British Medical Journal in April 1970. Their research found a 'positive correlation . . . between the dose of oestrogen [estrogen] and the risk of . . . cerebral thrombosis.' It also noted that estrogen dosage might not be the only factor related to the risk of thrombo-

embolism. Ortho has not claimed that it was unaware of this study, but the report was not cited in the package insert for the 2 mg. oral contraceptive or in the package insert for any other Ortho oral contraceptive; in fact, the insert for each of these products was identical.

. . . .

"The absence of any reference to the 1970 British study, which, unlike the four studies actually referred to in the package insert, would have provided numerical data to the physician on the dose-effect relationship between thromboembolic disease and oral contraceptives, was ground for a jury finding that the warnings were factually inadequate. To this is to be added the fact that the inserts for each of Ortho's oral contraceptives were identical, despite this evidence that higher-estrogen-dose pills might present greater risks to users. From this, the jury mght have concluded that the warnings for the 2 mg. pills were inadequate. The jury might also have considered on the question of warning the fact that the sales-person who regularly called on Dr. Campbell did not orally inform him that the 2 mg. drug appeared to present a higher risk of thrombo-embolism. See Sterling Drug, Inc.

v. Yarrow, 408 F.2d at 992, 993 (trial court may find it unreasonable to fail to instruct sales personnel to warn physicians on whom they call regularly of drug dangers; not clearly erroneous to find such sales personnel present most effective method of warning doctors).

"In view of the expert testimony that the April 1970 study did establish the existence of a positive correlation between the dose of estrogen and the risk of cerebral thrombosis, and the admitted fact that the labeling did not refer to this study, Ortho's claim that the Brochus did not provide expert testimony on the inadequacy of the label is untenable." 642 F.2d at 657-59.

One other case is illuminating. In Seley v. G. D. Searle & Co., 67 Ohio St. 2d 192, 423 N.E.2d 831 (1981), the Supreme Court of Ohio discussed the adequacy of warnings. It said:

"A jury may find that a warning is inadequate and unreasonable even

> where the existence of a 'risk,' i.e., a causal relationship between use of the product and resulting injury, has not been definitely established. McCue v. Norwich Pharmacal Co. (C.A. 1, 1972), 453 F.2d 1033; Hamilton v. Hardy, [37 Colo.App. 375, 549 P.2d 1099 (1976)]. Thus, where scientific or medical evidence exists tending to show that a certain danger is associated with use of the drug, the manufacturer may not ignore or discount that information in drafting its warning solely because it finds it to be unconvincing. Mahr v. G. D. Searle & Co. [72 Ill.App.3d 540, 390 N.E.2d 1214 (1979)], at page 564." (Emphasis supplied.) 67 Ohio St. 2d at 198

An enlightening discussion of recent cases involving the duty of an ethical drug manufacturer to warn is found in Scott, Products Liability, 1982 N.Y.U. Ann. Surv. Am. L. 709, 720-24:

"DUTY TO WARN OF THE DANGERS
INHERENT IN DRUGS

"Drug manufacturers have a duty to warn medi-cal practitioners about products which, though useful, are unavoidably unsafe. An unusual result was reached in Lukaszewicz v. Ortho Pharmaceutical Corp. [510 F.Supp. 961 (E.D. Wis. 1981)], where the District Court for the Eastern District of Wisconsin held that the manufacturer of an oral contraceptive had the duty to warn not only the doctor, but also the patient, of the potential risks involved in taking the drug. The court imposed this duty to warn even though the drug was available only by prescription.

"In Lukaszewicz, the plaintiff alleged that use of the contraceptive caused her to suffer severe migraine headaches which ultimately resulted in a cerebrovascular injury. She claimed that Ortho had a duty to warn patients directly of the possible side effects of the drug.

"The court based its decision on an FDA regu-lation which, when read together with Wisconsin law, spelled out a case for negligence per se. The FDA regulation sets out detailed instructions regarding the required warnings to be directed to

users of oral contraceptives in a package insert. While other federal courts have been aware of FDA regulations about drug labeling, the court noted that none has held that a drug manufacturer's duty extends beyond warning the doctor. The law in Wisconsin, however, provides that violation of state and federal legislative and administrative enactments designed to protect a particular class of persons, which results in the proscribed harm, constitutes negligence per se. The court, therefore, held that the defendant drug company breached its duty to the plaintiff, because the purpose behind the FDA regulation was to enable patients taking oral contraceptives to recognize harmful side effects and seek medical assistance, and because violation of the regulation by the manufacturer allegedly led to the harm which thc plaintiff suffered. The plaintiff's claim that she received no warning, as well as the issue of causation, became questions of fact for jury resolution.

"In light of the explicit requirements set out by the FDA regarding oral contraceptive labeling, the court's decision is clearly correct. Since there is no reason to promulgate regulations if they will not be enforced, one can only wonder why other courts have not

arrived at the conclusion reached in Lukaszewicz.

"In another case involving oral contraceptives, Brochu v. Ortho Pharmaceutical Corp. [642 F.2d 652 (1st Cir. 1981)], the Court of Appeals for the First Circuit, interpreting New Hampshire law, applied the strict liability standard to a prescription drug. The plaintiff's doctor had prescribed the defendant's two-milligram, high estrogen content oral contraceptive which the plaintiff took for over three years until, allegedly as a result of taking the drug, she suffered a stroke. The First Circuit upheld the plaintiff's claim that Ortho should have warned doctors that the estrogen content pill posed a high risk of cerebral damage and that failure to so warn rendered Ortho liable for manu-facturing a defective and unreasonably dangerous product.

"The court noted that certain drugs, though very useful, often cannot be made absolutely safe. Where such is the case, a manufacturer can avoid liability if it adequately warns of the dangers presented by the drug. An adequate warning is to be judged in light of what the manufacturer knew at the time the plaintiff took the drug. The court placed heavy emphasis on a

British study that established a positive correlation between a drug's estrogen content and the risk of stroke. The study had been published over a year before the plaintiff suffered her accident and yet Ortho did not mention the study in either the written or oral information it supplied to prescribing physicians. Additionally, in finding the warning accompanying the two-milligram contraceptive inadequate, the court noted that Ortho's labeling for all its oral contraceptives was identi-cal, despite evidence that the higher estrogen pills posed greater risks.

"The court next addressed the issue of causation and found that the defendant's failure to warn was the proximate cause of the plaintiff's injury. The plaintiff's doctor testified that if he had been alerted to the increased risk of the two-milligram pill he would not have prescribed it. The court held that, even if the doctor was careless in not prescribing the equally effective lower dosage pill, Ortho would not be relieved from liability because its failure to warn may have contributed to the doctor's carelessness.

"In contrast, the decision by the Court of Appeals for the Fourth Circuit in Stanback v. Parke-Davis

& Co. [657 F.2d 642 (4th Cir. 1981)] insulated a drug manufacturer from liability for failure to warn of the risks associated with its flu vaccine; the court affirmed the summary judg-ment granted to the defendant. The plaintiff in this case contracted Guillain-Barre Syndrome after being innoculated with the defendant's vaccine. She argued that the manufacturer's failure to pro-vide physicians with information about the risk of Guillain-Barre Syndrome constituted a breach of duty to warn of the potential dangers of the vaccine.

"The court, however, held that since the plaintiff was not able to show that the failure to warn was the cause of her injury, she could not recover from the manufacturer. Whether or not Parke-Davis breached its duty was considered irrelevant because there was clear evidence that the plaintiff's doctor was aware of the risk inherent in the vaccine but administered it anyway. The doctor also stated that he did not customarily pass on manufacturers' warnings to his patients. Therefore, reasoned the court, the doctor was an intervening cause, relieving the manufacturer of liability for its failure to warn.

"The three aforementioned cases can be reconciled by assessing what

each court thought may have been the potential effect of an adequate warning. In Lukaszewicz, a direct warning to the patient by means of a package insert may have alerted the plaintiff to the cause of her migraines and prompted her to seek medical attention in time to prevent any serious problem. Similarly, in Brochu, a warning to the patient's physician regarding the potential side effects of the two-milligram pill may have prompted him to prescribe a lower dosage, thus substantially reducing the patient's risk of injury. In Stanback, however, any warning the manu-facturer might have given apparently would have had no effect in light of the doctor's firm testimony that he would have administered the vaccine anyway. Here the manufacturer's breach of duty was not a cause of the plaintiff's injury. The Stanback court noted that had the testimony of the doctor indicated that he might have heeded a warning, a different result would have been reached. That result would have been identical to that reached in Brochu."

During the times relevant to this lawsuit, the label which accompanied

Ortho-Novum 1/80, when purchased by the patient, instructed the patient not to take the drugs without her doctor's continued supervision. It warned that the drug could cause side effects, but it did not elaborate upon those side effects except to say that the most serious known side effect was abnormal blood clotting. The "package insert" which is sent to the physician and which contains the information included in the Physicians' Desk Reference (PDR), an annual volume provided for use by physicians, presented detailed instructions, contraindications, warnings, and precautions. It is undisputed, however, that none of these warned of any possible association between the use of the product and HUS, malignant hypertension, or acute renal

failure. Dr. Hermes, plaintiff's gynecologist' testified in substance that he probably would have lowered the dosage had he been informed by Ortho of these potential dangers. Ortho had access to literature that should have prompted it to inform Dr. Hermes of what he needed to know. The expert testimony and the exhibits in this case disclose that there was an abundance of published information in the medical journals, prior to and during the years when plaintiff was taking Ortho-Novum 1/80, which linked the use of oral contraccptives with HUS, malignant hypertension, and acute renal failure. We agree with the McEwen and Seley courts. The available scientific literature clearly tended to show that there was danger of HUS, malignant hyper-

tension and acute kidney failure attendant to the use of the drug. Ortho, as an expert in the field, knew or should have known of the risk. We conclude that, on the basis of the evidence, Ortho had a duty to warn the prescribing physician, and the trial court properly submitted to the jury the issue of the adequacy of Ortho's published warning.

We hold that the manufacturer of an ethical drug has a duty to warn the medical profession of dangerous side effects of its products of which it knows, has reason to know, or should know, based upon its position as an expert in the field, upon its research, upon cases reported to it, and upon scientific development, research, and publications

in the field. This duty is continuing. We do not need to determine, in this case, what duty, if any, such a manufacturer has to warn the ultimate consumer, the patient. Here, neither was warned by Ortho, but Ortho's failure to warn the physician is sufficient to sustain the finding of negligence or breach of duty against it in this case.

Ortho also argues that the FDA has determined that contraceptive-induced HUS does not merit warnings, and that the courts of Kansas must defer to the FDA's determination. This argument centers around a letter from the FDA to Searle Laboratories. Searle had proposed fifteen or more package insert changes, covering many and varied subjects. Only

one of those mentioned the inclusion of HUS as a possible side effect. The FDA responded that it did not concur with the additional changes included in that proposal. This letter cannot be construed as a clear determination by the FDA that contraceptive-induced HUS does not merit warnings, and thus this argument has no merit.

FAILURE TO WARN AS CAUSATION

Ortho next contends that its failure to warn of the association between the use of its product and HUS, malignant hypertension, and acute renal failure was not a cause in fact of plaintiff's injury. To the contrary, we think the evidence was substantial that it was.

There was abundant evidence that the early diagnosis of HUS, of malignant hypertension, and of kidney failure is extremely important. In addition, Dr. Hermes testified that he has two of his daughters on a lower dosage of Ortho-Novum 1/50 because of what he has learned as a result of this case. There was evidence indicating that a lower dosage might have prevented HUS, and even if the higher dosage of estrogen contained in Ortho-Novum 1/80 were given, Mrs. Wooderson's attending physicians--if warned of the possibility of HUS--might have made an earlier diagnosis which, according to the expert testimony, might have averted the tragedy. Dr. Hermes testified that he is now alerted to the danger and would look for symptoms. The

duty to warn, of course, extends throughout the time that the plaintiff was taking Ortho-Novum 1/80. No warnings were given by Ortho during that period of time, and thus the physicians were not informed to be on the alert for symptoms of HUS, kidney failure, or malignant hypertension. The question of whether this failure to warn was a cause of plaintiff's injury was properly submitted to the jury. With respect to warnings, the Chapman court said:

> ". . . Comment j provides a presumption that an adequate warning would be heeded. This operates to the benefits of a manufacturer where adequate warnings in fact are given. Where warnings are inadequate, however, the presumption is in essence a presumption of causation." 180 Ind.App. at 55.

Similarly, the Seley court said:

> "'What the doctor might or might not have done had he been adequately warned is not an element plaintiff must prove as a part of her case.' Hamilton v. Hardy [37 Colo.App. 375, 549 P.2d 1099 (1976)], at page 387. The evidence provided by Dr. Froelich as to his independently acquired knowledge is insufficient to rebut the presumption established by Comment j." 67 Ohio St. 2d at 201-202.

In this case, the warning was inadequate. On the evidence before it, the jury was entitled to find that this inadequate warning caused Mrs. Wooderson's injuries.

Ortho also contends that plaintiff's other theories--failure to test and a "design defect" claim--are not supported by the evidence. The case was submitted

to the jury on the theory of failure to warn. Failure to test was mentioned in the instructions, but was not made a specific basis for recovery of compensatory damages. We will discuss it later in connection with the punitive damages issue. We note, however, that there was evidence on which the jury could have found that Ortho had not fully tested its product in that it had not examined certain renal blood vessels during its animal studies, after renal blood vessel lesions attributable to oral contraceptives had been reported. The design defect claim is based upon the fact that the dangers of HUS, malignant hypertension and acute kidney failure are considerably reduced when a lower dosage is administered, such as that contained

in Ortho-Novum 1/50. There was some evidence in the case to support this claim; however, the matter was not submitted to the jury and was not made a basis for recovery of compensatory damages. We find no error.

COMPARATIVE NEGLIGENCE

Ortho next argues that the trial court erred in refusing to submit the issue of comparative fault of the plaintiff and of the plaintiff's physicians, Dr. Hermes and Dr. Wilcox, to the jury. This argument is made in light of K.S.A. 60-258a, which reads in part as follows:

> "60-258a. Contributory negligence as bar to recovery in civil actions abolished, when; award of damages based on comparative negli-

gence; imputation of negligence, when; special verdicts and findings; joinder of parties; proportioned liability. (a) The contributory negligence of any party in a civil action shall not bar such party or said party's legal representative from recovering damages for negligence resulting in death, personal injury or property damage, if such party's negligence was less than the causal negligence of the party or parties against whom claim for recovery is made, but the award of damages to any party in such action shall be diminished in proportion to the amount of negligence attributed to such party. If any such party is claiming damages for a decedent's wrongful death, the negligence of the decedent, if any, shall be imputed to such party.

"(b) Where the comparative negligence of the parties in any such action is an issue, the jury shall return special verdicts, or in the absence of a jury, the court shall make special findings, determining the percentage of negligence attributable to each of the parties, and determining the total amount of damages sustained by each of the claimants, and the entry of judgment shall be made by the court. No general verdict shall be returned by the jury.

. . . .

> "(d) Where the comparative negligence of the parties in any action is an issue and recovery is allowed against more than one party, each such party shall be liable for that portion of the total dollar amount awarded as damages to any claimant in the proportion that the amount of his or her causal negligence bears to the amount of the causal negligence attributed to all parties against whom such recovery is allowed."

We have held that the intent and purpose of the legislature in adopting the statute is to impose individual liability for damages based on the proportionate fault of all of the parties to an occurrence which gave rise to the injuries and damages, whether or not those persons are joined formally as parties to the action. Brown v. Keill, 224 Kan. 195, 580 P.2d 867 (1978). We have also held that a defendant who seeks

to reduce his percentage of fault by comparing the fault of another party has the burden of proving the other party's fault by a preponderance of the evidence. McGraw v. Sanders Co. Plumbing & Heating, Inc., 233 Kan. 766, 667 P.2d 289 (1983). This follows the general rule that the burden of proof is upon the party asserting the affirmative of an issue. See Jensen v. Jensen, 205 Kan. 465, 467, 470 P.2d 829 (1970); Wycoff v. Board of County Commissioners, 191 Kan. 658, 665, 383 P.2d 520 (1963); 31A C.J.S., Evidence § 104; 29 Am. Jur. 2d, Evidence § 130.

Ortho, in its answer, alleged that if the plaintiff sustained injury, she was guilty of negligence which contri-

buted directly and proximately as a cause of her injuries, and that she failed to use the product in the manner intended. The answer also alleged that plaintiff's injuries, if any, were caused by the negligence of other parties for whom Ortho is not responsible. Dr. Hermes and Dr. Wilcox, who were plaintiff's gynecologists, were originally joined by the plaintiff as defendants in this action. They remained in the action at the time of the pretrial conference. At that time, the plaintiff enumerated various claims against Ortho, and she enumerated her claims of negligence as to Dr. Hermes and Dr. Wilcox. Ortho's position was fully set out in the resulting pretrial order, which included Ortho's claim that:

> "Plaintiff's injuries, if any, were caused by plaintiff's own causal negligence, or by the causal negligence of other defendants for whom this defendant is not responsible, and said negligence either individually or combined was equal to or greater than any causal negligence of this defendant . . . ."

Also included in the pretrial order was a specific designation of all of the witnesses, expert and lay, which each of the parties intended to call during the trial of this action, and all of the exhibits each intended to offer. During the pretrial conference, Ortho's position regarding the actions of Doctors Hermes and Wilcox was clarified as shown by the following excerpt of the transcript of that hearing:

> "MR. MICHAUD: Do you contend, Mr. Wall, any departure from stand-

ard approved medical practice on the part of the defendant doctors?

"MR. WALL: No.

"MR. MICHAUD: So, so far as you are concerned, they did nothing wrong in the use of Ortho-Novum in the plaintiff?

"MR. WALL: No.

. . . .

"MR. MICHAUD: All right, you are not contending in this case that the doctors did anything wrong?

"MR. WALL: No, Gerry.

. . . .

"MR. MICHAUD: Your Honor, I would ask the Court to require Mr. Wall to state whether or not it is one of their defenses in this case that the doctors did anything wrong insofar as causing plaintiff's injury.

. . . .

"MR. WALL: Gerry, I don't plan to bring any experts on that subject and have no reports. Now, if I was going to bring that kind of evidence, I would agree you are entitled to it.

"Now, I don't agree, though, however, that, if at the completion of Gerry's lawsuit, all of the evidence points to the doctor and is marginal as to me, that I am precluded from saying under the evidence that it would appear to me that the evidence against the defendant Ortho-Novum is slight or minimal, at least, and it appears that Mr. Michaud has produced a great case against the doctors, and I think based on the evidence you will find for the defendant Ortho-Novum. I am not precluded from that. I don't think Bud [Mr. H. W. Fanning, who then represented Dr. Hermes and Dr. Wilcox] can be precluded at the completion of saying the same thing.

"THE COURT: I understand what you are saying is you don't intend to offer any evidence that the doctors did anything wrong.

"MR. WALL: That's exactly right."

After the pretrial conference, and shortly prior to trial, plaintiff settled with Dr. Hermes and Dr. Wilcox, with the

result that there remained no claims against the two treating physicians at the time of trial. After settlement, both doctors made motions for summary judgment which were sustained by the trial court. We do not deem it important to this discussion to deal with the mechanics by which the physicians were removed from the case; a simple dismissal of plaintiff's claims, with prejudice, would have accomplished the same result. Ortho objected to the dismissal of the physicians, and at trial sought to have their negligence compared. The trial court said:

> "My conclusion is simply that as far as what's happened, the machinery was there and any time Ortho wanted to put the negligence of the doctors in issue as between Ortho and the doctors, they could

> have done that. . . . Mr. Michaud's questions at the Pretrial Conference were nothing less than an invitation to do that. The invitation was declined. . . . All negligence of the doctors has been removed by Mr. Michaud from this action. It's not in issue. It will not be compared. We are directly at issue with the questions raised by the plaintiff against the defendant Ortho."

As discussed at length earlier in this opinion, plaintiff's principal claim against Ortho was that it failed to give an adequate warning to her physicians of the possibility that Ortho-Novum 1/80 could cause HUS, malignant hypertension or acute renal failure. It was undisputed that no such warning was specifically given in the literature provided by Ortho to the physicians. Ortho was hardly in a position to come forth with a vigorous assertion that the physicians

were negligent in their treatment of the plaintiff since Ortho had not warned the physicians of the risks and had not alerted them. Plaintiff's counsel, at pretrial, was concerned with Ortho's position, as reflected in the discussion quoted above. If no settlement was effected, plaintiff needed to be prepared to meet any evidence produced by Ortho of the negligence of the treating physicians. Ortho's position was clearly stated: It made no claim that the physicians departed from approved medical practice, and if intended to offer no evidence that the physicians did anything wrong. If the plaintiff's evidence were to disclose fault on the part of the physicians, Ortho reserved the right to argue that. When the matter

went to trial, plaintiff offered no evidence of causal negligence on the part of the physicians, and thus it was not necessary for the trial court to submit that issue to the jury. There was no evidence, expert or otherwise, of actionable, causal negligence on the part of Drs. Hermes and Wilcox. Under the circumtances disclosed by the record and the evidence in this case, we conclude that the trial court did not err in refusing to submit the issue of the comparative negligence of the physicians to the jury.

As to the claimed negligence on the part of the plaintiff, Ortho points only to the evidence that plaintiff did not go to the hospital emergency room on June 25 after she was told by her physician to do

so if she did not get better by 6:00 o'clock that evening. Whether she felt better by evening, we do not know. There is no testimony, medical or otherwise, which suggests that this failure to go to the hospital on June 25 caused or contributed to her injuries or that her condition was reversible on June 25. She saw Dr. Wilcox on June 28, and he did not send her to the hospital at that time. There is, however, testimony that diagnosis and treatment several months earlier might have averted the disaster. We find no evidence to support the submission of Mrs. Wooderson's causal negligence to the jury.

THE PUNITIVE DAMAGE CLAIM

Ortho next claims that the punitive

damage claim should not have been submitted to the jury. It contends that the failure to warn of all potential dangers which an inherently dangerous product such as a prescription drug might cause cannot support a punitive damage award. It contends that there was no evidence of a willful or wanton failure to warn of a known or established defect or danger. It contends that in 1976 there was at most a suggestion that oral contraceptives caused HUS and that the existence of this "suggestion" has neither been confirmed nor refuted; therefore, without proof that there is in fact an increased risk, there is no proof that Ortho willfully failed to warn of the risk. Plaintiff contends that punitive damages were proper because Ortho failed to warn of

HUS, malignant hypertension, vessel wall damage and acute kidney failure after it knew or should have known of the risks, and--in effect--that Ortho put its own financial interests ahead of its duty to the patients taking its pharmaceuticals. We note that it was not until January, 1977, after plaintiff's kidneys failed, that Ortho first included in its package insert a warning under "adverse reactions reported in users of oral contraceptives," an association neither confirmed nor refuted, of "impaired renal function." Even that and later package inserts do not warn of acute renal failure, malignant hypertension, or HUS.

It will be helpful here to review briefly some of the applicable rules

governing punitive damages. In Cantrell v. R. D. Werner Co., 226 Kan. 681, 602 P.2d 1326 (1979), we said:

> "The Court of Appeals has recently given an expansive discussion of the rules relating to punitive damages in the case of Sanders v. Park Towne, Ltd., 2 Kan.App.2d 313, 318-19, 578 P.2d 1131, rev. denied 225 Kan. 845 (1978):
>
> '[P]unitive damages "are permitted whenever the elements of fraud, malice, gross negligence, or oppression mingle in the controversy. (Malone v. Murphy, 2 Kan. 250; Albert Wiley v. Keokuk, 6 Kan. 94; and Cady v. Case, 45 Kan. 733, 26 Pac. 448.) Such damages are allowed not because of any special merit in the injured party's case, but are imposed by way of punishing the wrongdoer for malicious, vindictive or a willful and wanton invasion of the injured party's rights, the purpose being to restrain and deter others from the commission of like wrongs. (Stalker v. Drake, 91 Kan. 142, 136 Pac. 912; see, also, Townsend v. Seefeld, 102 Kan. 302, 169 Pac. 1157; 15 Am. Jur., Damages, § 266, p. 700.)" Watkins v. Layton,

182 Kan. 702, 705, 324 P.2d 130 (1956).' See also Newton v. Hornblower, Inc., 224 Kan. 506, 582 P.2d 1136 (1978); Koch v. Merchants Mutual Bonding Co., 211 Kan. 397, 402, 507 P.2d 189 (1973).

"In Henderson v. Hassur, 225 Kan. 678, 594 P.2d 650 (1979), this court stated:

'The law establishes no fixed ratio between actual and exemplary damages by which to determine excessiveness. In assessing punitive damages the nature, extent, and enormity of the wrong, the intent of the party committing it, and all circumstances attending the transaction involved should be considered. Any mitigating circumstances which may bear upon any of the above factors may be considered to reduce such damages. Will v. Hughes, 172 Kan. 45, 55, 238 P.2d 478 (1951). In fixing an award of punitive damages a jury may consider the amount of actual damages recovered, defendant's financial condition and the probable litigation expenses. Ayers v. Christiansen, 222 Kan. 225, 229, 564 P.2d 458 (1977).' p. 694." 226 Kan. at 686.

In Restatement (Second) of Torts §908 (1977), we find the following:

> "(1) Punitive damages are damages, other than compensatory or nominal damages, awarded against a person to punish him for his outrageous conduct and to deter him and others like him from similar conduct in the future.
>
> "(2) Punitive damages may be awarded for conduct that is outrageous, because of the defendant's evil motive or his reckless indifference to the rights of others. In assessing punitive damages, the trier of fact can properly consider the character of the defendant's act, the nature and extent of the harm to the plaintiff that the defendant caused or intended to cause and the wealth of the defendant."

And see also Binyon v. Nesseth, 231 Kan. 381, 386, 646 P.2d 1043 (1982), affirming the Court of Appeals opinion in the same case, 7 Kan.App.2d 110, 638 P.2d 946 (1981); Kearney v. Kansas Public Service Co., 233 Kan. 492, 503, 665 P.2d 757 (1983); Ettus v. Orkin Exterminating

Co., 233 Kan.555, 567-68, 665 P.2d 730 (1983); Kline v. Multi-Media Cable-vision, Inc., 233 Kan. 988, 989, 666 P.2d 711 (1983) and Newton v. Hornblower, Inc., 224 Kan. 506, 524 -525, 582 P.2d 1136 1978).

The issue before us on this point is whether, viewed in the light most favorable to the plaintiff, there is evidence from which a jury could have found the defendant to be grossly negligent or recklessly indifferent to the rights of others.

Ortho is the manufacturer of a dangerous prescription drug Ortho-Novum 1/80. Therefore, Ortho is under a duty to make known to the medical profession,

or at least those physicians who are prescribing that drug, any of the dangerous side effects of which it knows or has reason to know. As the Oregon court observed in McEwen:

> "[T]he drug manufacturer is treated as an expert in its particular field, and is under a 'continuous duty * * * to keep abreast of scientific developments touching upon the manufacturer's product and to notify the medical profession of any additional side effects discovered from its use.' [Citations omitted.] The drug manufacturer's duty to warn is, therefore, commensurate not only with its actual knowledge gained from research and adverse reaction reports but also with its constructive knowledge as measured by scientific literature and other available means of communication." 270 Or. at 386.

The scientific evidence presented by the plaintiff disclosed that there were

twenty-one reported cases of women on oral contraceptives having HUS before the plaintiff presented that syndrome. At the time of trial there were some thirty-nine patient cases reported wherein oral contraceptives were associated with HUS. Nevertheless, there had never been a warning of any possible association between the use of Ortho-Novum 1/80 and HUS, malignant hypertension, vessel wall damage or acute renal failure contained within defendant's package inserts or within its PDR insertion. Even before plaintiff's renal failure, there were many articles in scientific journals linking oral contraceptives with these extremely serious conditions. As the Ohio Supreme Court noted in Seley:

> "[W]here scientific or medical evidence exists tending to show that a certain danger is associated with use of the drug, the manufacturer may not ignore or discount that information in drafting its warning solely because it finds it to be unconvincing." 67 Ohio St. 2d at 198. (Emphasis supplied.)

We agree, and we also think that the duty of the manufacturer must be commensurate with the seriousness of the danger. The greater the danger, the greater the duty.

One of the many documents in evidence is a "Dear Doctor" letter, sent nationally to all physicians by the acting commissioner of the Food and Drug Administration on January 12, 1970. The letter reads in part:

> "I am enclosing revised labeling for oral contraceptives to

reflect the latest findings on safety and efficacy, as reported by the Obstetrics and Gynecology Advisory Committee in August 1969. An American study confirms previously reported studies in Great Britain which show a relationship between the use of oral contraceptives and the occurrence of certain thromboembolic diseases. These carefully designed retrospective studies show that users of oral contraceptives are more likely to have thrombophlebitis and pulmonary embolism than non-users. Studies in Great Britain also show increased risk of cerebral thrombosis and embolism in users of oral contraceptives. A British study found a hospitalization rate (an index of morbidity) in women age 20-44 to be 47 per 100,000 in users compared to five per 100,000 in non-users.

"The American study, although not designed to evaluate differences between products, also suggests there may be an increased risk of thromboembolic disease in users of sequential products. This difference in risk cannot be quantitated, and further studies are needed to confirm the observation.

> "The British Committee on Safety of Drugs recently advised practitioners in that country that only products containing 0.05 mg. or less of estrogen should normally be prescribed because reports of suspected adverse reactions indicated there is a higher incidence of thromboembolic disorders with products containing 0.075 mg. or more of estrogen than with products containing the smaller dose. This finding has not been confirmed by other studies.
>
> . . . .
>
> "I also request your assistance in continuing our assessment of the safety of oral contraceptives. Your reports of adverse reactions will help us to do this." (Emphasis supplied.)

Ortho-Novum 1/80 contains 80 micrograms (gammas) of estrogen, while Ortho-Novum 1/50 contains 50 micrograms of estrogen. On April 10, 1970, Ortho sent

a Sales Bulletin on the subject of Ortho-Novum labeling changes to its "detail men," sales representatives of the manufacturer who call directly upon physicians. That bulletin quoted extensively from the first paragraph of the acting commissioner's letter, but made no mention of the third paragraph concerning the British Committee's advice to physicians in England. On May 15, 1970, Ortho sent out another Sales Bulletin, this one on the subject of The Report of the British Committee on the Safety of Drugs. This bulletin did not quote the third paragraph of the acting commissioner's letter, but was obviously written in response thereto. It indicated that Ortho's own analysis of the British data indicates that there is no statis-

tically significant difference between 50, 75/80 and 100 micrograms of mestranol. It stated that products containing 75/80 gammas of mestranol show a risk as low if not lower than 50 gamma products. It urged the continued sale of its 80 gamma product, and cautioned its sales people not to be "stampeded" with the number 50. A July 6, 1970, Sales Bulletin continued to urge sale of Ortho-Novum 1/80, and urged concentration on Ortho-Novum 1/50 only if the physician "is very concerned with using lowest estrogen activity." For physicians who asked about switching patients to lower estrogen level products, the bulletin suggested the detail men respond:

> "Doctor, nothing in this British data offers enough sound evidence to

> cause you to switch patients who are on 100 gamma of mestranol. We have been saying for years and continue to say that it makes sense to use the least activity of any drug that will effectively accomplish its purpose; therefore, you may wish to move patients to low activity products such as ORTHO-NOVUM 1/80 or ORTHO-NOVUM 1/50."

In short, this evidence indicated that Ortho played down the British report and continued to urge sale of its higher estrogen product until Ortho itself could be entirely satisfied that the product was causing damage. Apparently its competitive position in the market was better served by continuing the manufacture and sale of its 1/80 product, since other manufacturers were also producing the 1/50 dosage.

Another area which plaintiff emphasizes is that of the "Irey-type" lesions. Dr. Nelson S. Irey, of the Armed Forces Institute of Pathology, issued a report in 1969, and published it in a pathology journal in 1970. The blood vessels of some forty women had been examined posthumously. Lesions were found in the inner wall or intima of the blood vessels of every one of the bodies of those women who were known to have been taking oral contraceptives; no such changes were found in the bodies of those who had <u>not</u> been taking oral contraceptives. In spite of this report linking oral contraceptives to vessel wall damage, Ortho did no further animal research to prove or disprove the proposition put forth by Irey: that oral contraceptives cause

vessel wall damage. The pathologist who examined plaintiff's kidney tissue found lesions to the intima or inner lining of the blood vessels in her kidneys remarkably similar to those lesions reported by Dr. Irey in his 1969 study.

We conclude that there was scientific and medical evidence tending to show that vessel wall damage, acute renal failure, malignant hypertension and HUS were extremely serious dangers which were associated with Ortho's product; that Ortho chose to ignore the accumulating medical and scientific evidence; that Ortho did not pursue the additional research which the data suggested; that Ortho continued to urge the use of its higher estrogen preparations, played down

the danger of those products, and gave physicians no warning of the dangers involved. From this evidence, the jury could have found that Ortho was grossly negligent and recklessly indifferent to the rights of others, including this plaintiff. The trial court did not err in submitting the issue of punitive damages to the jury.

Ortho argues that the mere submission of the punitive damage claim was so inflammatory and prejudicial that it requires that a new trial be granted on liability for compensatory damages. We have reviewed the court's instructions, the arguments of counsel and the court's ruling thereon, and find no error.

Ortho claims that the punitive damage award was so large as to shock the conscience. An award of $2,750,000 is, of course, enormous. The verdict of $2,000,000 for actual damages was also enormous. As we noted earlier in this opinion, Ortho does not challenge the award of actual damages; it does not argue that the $2,000,000 awarded as compensatory damages is excessive, or that the amount of that award is not supported by the evidence. The actual out-of-pocket medical expenses of the plaintiff were enormous; her injuries were enormous; and her injuries are continuing and permanent. The punitive damage award must be viewed in light of the actual damages sustained, the actual damage award, the circumstances of the

case, the evidence presented, the relative positions of the plaintiff and the defendant, and the defendant's financial worth. Upon a review of this record, we cannot find that an award of less than one and one-half times the actual damages as punitive damages is excessive.

Ortho also contends that the admission of evidence of its size and profits was error. We need not discuss this at length, however, for it is the rule in this state that the defendant's financial circumstances are relevant to the issue of punitive damages. See Ettus v. Orkin Exterminating Co., 233 Kan. 555, Syl. ¶ 7, 665 P.2d 730 (1983). The trial court did not err in admitting this evidence.

MITIGATING CIRCUMSTANCES and SUBSEQUENT REMEDIAL CONDUCT

Ortho argues that the trial court erred in refusing to permit Ortho to present evidence of "mitigating circumstances," and that the trial court erred in admitting evidence of "subsequent remedial conduct." We have reviewed the evidence targeted in these arguments and find no error. Ortho wished to introduce evidence of the benefits of oral contraceptives with regard to safety and effectiveness. There was much evidence in the record of the almost universal use of oral contraceptives, and no modern jury could be unaware of the widespread use and effectiveness and of the usual safety of oral contraceptives. The particular

evidence Ortho wished to introduce, however, was not evidence of "mitigating circumstances." That the product is widely used, ordinarily safe, and ordinarily effective, does not excuse the manufacturer's failure to warn of dangerous side effects of which the manufacturer knows or has reason to know. Evidence of widespread and beneficial use, and of usual safety and effectiveness, is not evidence of "mitigating circumstances," and the trial court did not err in excluding it.

The evidence of "subsequent remedial conduct" was not such as to come within that description. It was evidence of contacts between Ortho's Director of Medical Services and Dr. Diederich, fol-

lowing plaintiff's bout with HUS. Much of the discussions about which Ortho complains took place out of the hearing of the jury. The evidence admitted was offered only to show Ortho's continuing course of conduct--receipt of information linking high estrogen oral contraceptives with HUS, vessel wall damage, loss of kidneys, acute hypertension--and a continuing failure of Ortho to include warnings of these dangers to prescribing physicians or users of the products. We find no error in the admission of this evidence.

Finally, Ortho argues error in the admission or rejection of certain documentary evidence. This was a lengthy trial, carefully tried by able and

experienced counsel. We have carefully examined the record and find no prejudicial or reversible error. The judgment is affirmed.

SCHROEDER, C.J., dissenting: This is a comparative negligence action brought by the plaintiff Carol Lynn Wooderson, to recover damages for personal injuries which she claims resulted from ingestion of the oral contraceptive Ortho-Novum 1/80 over a period of years. The defendants named when the action was filed were the Ortho Pharmaceutical Corporation (Ortho) and the plaintiff's gynecologists, Dr. Hermes and Dr. Wilcox.

The plaintiff alleged negligence on the part of her doctors and on the part

of Ortho. When the pretrial conference was conducted the doctors were represented by counsel in the action and the plaintiff was pursuing her action against the doctors as well as Ortho.

After the pretrial conference and shortly prior to trial, the plaintiff settled with the two doctors who in turn moved for summary judgment which the trial court sustained. This court in its majority opinion gratuitously states, "a simple dismissal of plaintiff's claims, with prejudice, would have accomplished the same result." Ortho objected to the dismissal of the physicians, and at trial sought to have their negligence compared. The trial court ruled in substance that the negli-

gence of the doctors had been removed by counsel for the plaintiff from this action and the court was concerned only with questions raised by the plaintiff against the defendant Ortho.

This, in my opinion, was reversible error for the following reasons.

In its answer Ortho alleged that if the plaintiff sustained injury, she was guilty of negligence which contributed directly and proximately as a cause of her injuries, and that she failed to use the product in the manner intended. The answer of Ortho was also alleged that the plaintiff's injuries, if any, were caused by the negligence of other parties for whom Ortho is not responsible.

Addressing the comparative negligence statute, K.S.A. 60-258a, the court in its opinion says:

> "We have held that the intent and purpose of the legislature in adopting the statute is to impose individual liability for damages based on the proportionate fault of all of the parties to an occurrence which gave rise to the injuries and damages, whether or not those persons are joined formally as parties to the action." (Emphasis added.)

The court properly cites Brown v. Keill, 224 Kan. 195, 580 P.2d 867 (1978), for this proposition. However, from this point on in the opinion the court completely ignores Brown v. Keill without further comment on the validity of this precedent. Brown v. Keill was reaffirmed and asserted as controlling law on the

proposition above stated in Gaulden v. Burlington Northern, Inc., 232 Kan. 205, 654 P.2d 383 (1982). There a factual situation similar to the instant case was presented in a case involving the Federal Employers' Liability Act, 45 USCA § 51 et seq., (FELA). The plaintiff sued the railroad and Jack James. Later the plaintiff settled with James and the trial court dismissed James from the lawsuit. Even though the plaintiff was entitled to recover the entire judgment, less the plaintiff's percentage of negligence, from the railroad, the trial court was reversed and the case was sent back for a new trial with instructions that the neglilgence of James must be compared with that of the plaintiff and the railroad on the authority of Brown v. Keill,

and other cases cited therein. The court referred to the comparative negligence statute, K.S.A. 60-258a, and said:

> "The purpose of that statute is to impose individual liability for damages based upon proportionate fault. The concept of joint and several liability between joint tortfeasors no longer applies, and since individual judgments will be based upon proportionate fault, contribution among joint judgment debtors is no longer required. Brown v. Keill, 224 Kan. 195, 580 P.2d 867 (1978). . . .
>
> . . . .
>
> "We have consistently held that all issues of liability, including the causal negligence or fault of all parties to an occurrence, should be determined in one lawsuit, whether the participants are all formally joined as parties to that lawsuit or not. Brown v. Keill, 224 Kan. 195; Eurich v. Alkire, 224 Kan. 236, 579 P.2d 1207 (1978); Albertson v. Volkswagenwerk Aktiengesellschaft, 230 Kan. 368, 634 P.2d 1127 (1981); and Lester v. Magic Chef, Inc., 230 Kan. 643, 641 P.2d 353 (1982)." (Emphasis added.) 232 Kan. at 212-13.

In the case at bar, the trial court granted summary judgment for the doctors on their own motion, and ruled their negligence was no longer an issue. It then declared the sole remaining issue of negligence to be the adequacy of the warning given the doctors by Ortho in the distribution of its prescription drug, for which negligence if any, the plaintiff was entitled to recover damages. By this ruling the plaintiff was insulated at the trial against any charge of negligence.

By this procedure, and the instructions given by the trial court, Ortho was stymied. In substance, the jury was permitted to have only tunnel vision focused upon Ortho to respond for the total damages suffered by the plaintiff.

It cannot be successfully argued the doctors were not negligent in the administration of this prescription drug, or in their treatment of this young plaintiff, after her blood pressure in December 1974 was diagnosed by them as high, simply because the plaintiff settled with them. The plaintiff sued them charging negligence and pursued her claim against them. Only after settlement was a summary judgment sustained on the doctors' own motion.

The jury in this comparative negligence action should have been permitted to consider the negligence of all parties to the occurrence in order to fulfill the intent of the comparative negligence statute to impose individual liability

for damages based upon proportionate fault. See Gaulden v. Burlington Northern, Inc., 232 Kan. at 212-13.

For the court to declare, as a matter of law, that there was no evidence for the jury to consider on the issue of plaintiff's contributory negligence is presumptuous and speculative. The plaintiff, a young woman just married in 1972 and in good health, was diagnosed by her doctor as having high blood pressure (130/80) in December 1974, and again (120/90) in January 1976. She did not return to her doctor's office again until June 28, 1976, although she called in giving her symptoms on May 4, 1976, as a cold and on June 25, 1976, as stomach pains and vomiting. These facts in the

record must be viewed in light of a situation where the doctors have been erroneously removed from the case as parties whose negligence should have been considered. Had the case been tried with the doctors in the case for comparison of their negligence with that of the plaintiff and Ortho, the evidence may have been substantially different. The simple issue upon which the trial court admitted relevant evidence would have been expanded to other issues upon which evidence excluded would have been relevant.

By limiting the jury to the issue tried, the entire injury and resulting damages to the plaintiff were heaped upon Ortho. With the entire focus upon Ortho

and with the nature and extent of plaintiff's damages, it was not difficult for plaintiff's counsel to convince the jury to award substantial punitive damages. In fact, had the negligence of all parties been submitted to the jury the actual damages may have been much less and there may have been no punitive damages awarded.

It is respectfully submitted the judgment of the trial court should be reversed and a new trial granted in conformity with the law of comparative negligence as heretofore announced by the Supreme Court.

IN THE SUPREME COURT OF THE
STATE OF KANSAS

Carol Lynn Wooderson, Appellee,

v.

Ortho Pharmaceutical Corporation,
et al., Appellants.

You are hereby notified of the following action taken in the above entitled case:

Motion by Appellant for Rehearing.

Considered and Denied

Motion by Appellant Ortho Pharmaceutical Corporation pursuant to 28 U.S.C. § 2101(f) for stay of mandate and execution of judgment pending application to the Supreme Court of the United States for Writ of Certiorari.

Mandate is stayed until August 6, 1984, to allow defendant to petition for certiorari.

Yours very truly,

LEWIS C. CARTER
CLERK, SUPREME COURT

Date: June 25, 1984

APPENDIX B

APPENDIX B

STATUTES INVOLVED

§ 201(n) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 321:

> (n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in

> the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

§ 502(a) and (n) of the Act, 21 U.S.C. § 352:

> A drug . . . shall be deemed to be misbranded (a) if its labeling is false or misleading in any particular
>
> . . .

(n) . . . In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of. . . (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 371(e) of this title.

§ 505(a) and (d)(6) of the Act, 21 U.S.C. § 355:

> (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug. If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that . . . based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application.